Remarks

Amendments to the Claims

The amendments to the claims do not add new matter. Support for the recitation in claims 1 and 8 that the immunogen is expressed *in vivo* by cells of the mammal is found at page 2, lines 7-8. Support for the recitation in claims 1 and 8 that the non-mammalian host cell is unable to use its own machinery to express the encoded immunogen is found at page 6, lines 15-17. Support for the recitation in claim 8 that an immune response is generated in the mammal against the immunogen is found, *inter alia*, at page 7, lines 14-16. Support for the recitation of a non-mammalian host cell is at page 4, line 29 to page 6 line 3, and at page 18, lines 13-17. These disclosures also support new claims 23-44. Support for the recitation in claims 1 and 8 of a promoter functional in a eukaryotic cell is at page 6, lines 9-13.

Rejection Under 35 U.S.C. § 102(b)

Claims 1, 3, 5-8, 10, 12 and 14 stand rejected under 35 U.S.C. § 102(b) as anticipated by Sumimoto (*Int. J. Cancer*, 1997, 7:556-561). On page 3, the Office Action cites Sumimoto as teaching "plasmid DNA encoding GM-CSF is inherently released into cells of the mammal and 'expressed.'" Applicant respectfully traverses the rejection.

To reject a claim as anticipated, each and every element as set forth in the claim must be either expressly or inherently described in a single prior art reference. *Verdegaal Bros. v. Union Oil Co., of California*, 814 F.2d 628, 631, 2 U.S.P.Q.2d (BNA) 1051, 1053 (Fed. Cir. 1987). Sumimoto does not meet this standard for either of independent claims 1 or 8. Each of claims 1 and 8 as amended recites that the administered host cell is non-mammalian. Sumimoto does not teach a non-mammalian host cell. Sumimoto investigated tumor vaccines using Lewis Lung

Carcinoma cells, which are derived from a mouse and therefore are mammalian cells. Sumimoto thus does not anticipate amended claims 1 or 8, dependent claims 3, 5-7, 10, 12, or 14, or new claims 23-44.

Please withdraw the rejection.

Rejection Under 35 U.S.C. § 102(a) over Kojima

Claims 1, 3, 5-8, 10, 12 and 14 stand rejected under 35 U.S.C. § 102(a) as anticipated by Kojima (*Human Gene Therapy*, May 20, 2003; 14:715-728). The Patent Office contends that the claims are anticipated for the same reasons as in the rejection based on Sumimoto. Applicant respectfully traverses the rejection.

Like Sumimoto, Kojima does not anticipate the claimed subject matter because Kojima does not teach non-mammalian host cells. The section titled "Cell lines and animals" on page 716 of Kojima discloses three cell lines: Lewis Lung Carcinoma, RMA, and YAC-1. All are murine. Kojima thus teaches only mammalian cells. Kojima therefore does not anticipate amended claims 1 or 8 or dependent claims 3, 5-7, 10, 12, or 14, or new claims 23-44.

Please withdraw the rejection.

Rejection Under 35 U.S.C. § 102(a) over Li

Claims 1, 2, 5-9, 12 and 13 stand rejected under 35 U.S.C. § 102(a) as anticipated by Li (*J. Allergy Clin. Immunol.* July 2003, 112:159-167). Applicant respectfully traverses the rejection.

Amended claims 1 and 8 recite a polynucleotide which comprises a promoter functional in a eukaryotic cell. Li teaches protein expressed in *E. coli* from pET vectors. See Li, page 160,

col. 2, lines 30-33. pET vectors are designed for expression in prokaryotic cells: "The pET System is the most powerful system yet developed for the cloning and expression of recombinant proteins in *E. coli*."[1] Li therefore does not anticipate claims 1 or 8, dependent claims 2, 5-7, 9, 12, or 13 or new claims 23-44.

Please withdraw the rejection.

Rejection Under 35 U.S.C. § 102(a) over Xu

Claims 1, 2, 5-9, 12 and 13 stand rejected under 35 U.S.C. § 102(a) as anticipated by Xu (*Vaccine*, 21: 644-648). The Patent Office contends that "the 'attenuated' Shigella of Xu are 'inactivated' as claimed because they are not able to proliferate in or spread between mammalian cells." Office Action at page 4. Applicant respectfully traverses the rejection.

Claims 1 and 8 recite administering a non-mammalian host cell wherein the non-mammalian host cell is unable to use its own machinery to express the encoded immunogen. Xu does not teach a non-mammalian host cell unable to use its own machinery to express the encoded immunogen. Xu's attenuated Shigella cell (strain *rfbF*) is able to use its own machinery to express the encoded immunogen: "The *rfbF* (pCMVH.gag) bacteria alone, without invasion of the mammalian cells, expressed a low amount of Gag protein." Page 646, Col.1, lines 22-27. Xu therefore does not anticipate claims 1 or 8, dependent claims 2, 5-7, 9, 12, or 13 or new claims 23-44.

Please withdraw the rejection.

[1] Novagen pET System Manual, 11th Edition, page 3, lines 1-2. A copy is provided with the accompanying Information Disclosure Statement.

Rejections Under 35 U.S.C. § 103(a)

Claims 1-13 stand rejected under 35 U.S.C. § 103(a) as obvious based on each of Sumimoto, Kojima, Li, and Xu in view of the state of the art at the time of filing (*i.e.*, because methods of inactivating cells were "standard in the art at the time of filing"). Office Action at page 5. Applicants respectfully traverse the rejection.

To establish a *prima facie* case of obviousness, the Supreme Court requires that the Patent Office supply "some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *KSR Int'l v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007) (quoting *In re Kahn*, 441 F.3d 977, 988, Fed. Cir. 2006).

Amended claims 1 and 8 recite administering an non-mammalian host cell to a mammal wherein the non-mammalian host cell is unable to use its own machinery to express the encoded immunogen, wherein the host cell comprises a polynucleotide which comprises a promoter functional in a eukaryotic cell and encodes an immunogen and wherein the immunogen is expressed by the cells of the mammal. None of the cited references teaches or suggests this subject matter, and the Office Action does not supply a rationale to explain how a skilled artisan could arrive at this subject matter in view of any of Sumimoto, Kojima, Xu, or Li.

Neither Sumimoto nor Kojima teaches or suggests an inactivated non-mammalian host cell or that an immunogen encoded by such cells can be expressed by the cells of a mammal to which the cells are administered. Li does not teach a polynucleotide comprising a promoter functional in a eukaryotic cell. Xu does not teach or suggest a non-mammalian host cell unable to use its own machinery to express the encoded immunogen.

To support an obviousness rejection, the Patent Office must make explicit a rationale underpinning the rejection. The Office Action does not contain a rationale for why one of

ordinary skill in the art would have been motivated to modify the teachings of any of Sumimoto, Kojima, Xu, and Li to arrive at the claimed subject matter. These arguments apply with equal force to new claims 23-44.

Please withdraw the rejections.

Respectfully submitted,

BANNER & WITCOFF, LTD.

/Lisa M. Hemmendinger/

Date: December 19, 2008

By: _____
Lisa M. Hemmendinger
Registration No. 42,653

Customer Number 22907
202-824-3000